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PATENT 2257-1-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : ANDREW WILLIAM HEATH
SERIAL NO. : 08/878,348 EXAMINER : P. GAMBEL
FILED : JUNE 18, 1997 ART UNIT : 1644
FOR : NOVEL VACCINE DEVELOPMENT

#170 7/22/00
T. Gray

Certificate of Mailing Under 37 CFR 1.8

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(Signature and Date)

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AMENDMENT UNDER 37 C.F.R. 1.111

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231

Sir:

In response to the outstanding Office Action dated March 3, 2000, and in accordance with Rule 111 of the Rules of Practice, please consider the following amendments and remarks. The Applicant also submits concurrently herewith a Petition for Extension of Time for one month, to and including July 3, 2000, accompanied by the required fee.

Please amend the above-identified Application as follows:

1. (Thrice Amended) An immunogenic composition [comprising] consisting essentially of an adjuvant and an antigen; wherein said adjuvant and said antigen are joined together; wherein said adjuvant is selected from the group consisting of an antibody that binds cell surface receptor CD40, a part of said antibody that is effective at binding CD40, and a CD40 ligand; and wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in activating said B-lymphocyte cell.

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2. (Twice Amended) A vaccine consisting essentially of an adjuvant and an antigen;
wherein said adjuvant is selected from the group consisting of an antibody that binds cell
surface receptor CD40, a part of said antibody that is effective at binding CD40, and a CD40
ligand;

wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in
activating said B-lymphocyte cell; and

wherein the vaccine promotes Ig secretion and isotype switching [including the
immunogenic composition according to Claim 1].

D² 13. (Twice Amended) A vaccine ~~according to Claim [2]~~ 12 further comprising at least
one cytokine.

15. (Twice Amended) A method for the manufacture of a vaccine capable of enhancing
immunity comprising

(a) selecting a suitable T-cell dependent and/or T-cell independent antigen, or parts
thereof, and

D³ (b) associating or combining said antigen with an adjuvant; wherein said adjuvant is
[adapted to stimulate B-lymphocyte receptor, CD40] selected from the group consisting of an
antibody that binds cell surface receptor CD40, a part of said antibody that is effective at binding
CD40, and a CD40 ligand;

wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in
activating said B-lymphocyte cell; and

wherein the vaccine promotes Ig secretion and isotype switching.

D⁴ 17. (Twice Amended) A kit for the manufacture of a vaccine capable of enhancing T-cell
independent or T-cell dependent immunity comprising a cell expressing a selected T-cell
dependent and/or T-cell independent antigen, or parts thereof, and an adjuvant [capable of
stimulating a B-lymphocyte receptor, CD40] selected from the group consisting of an antibody
that binds cell surface receptor CD40, a part of said antibody that is effective at binding CD40,

and a CD40 ligand;

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wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in activating said B-lymphocyte cell; and

wherein the vaccine promotes Ig secretion and isotype switching.

Please add the following new Claims:

-- 24. A vaccine consisting essentially of an adjuvant and one or more antigens;

wherein said adjuvant is selected from the group consisting of an antibody that binds cell surface receptor CD40, a part of said antibody that is effective at binding CD40, and a CD40 ligand;

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wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in activating said B-lymphocyte cell; and

wherein the vaccine promotes Ig secretion and isotype switching.

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25. A vaccine comprising an adjuvant and an antigen;

wherein said adjuvant is selected from the group consisting of an antibody that binds cell surface receptor CD40, a part of said antibody that is effective at binding CD40, and a CD40 ligand;

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wherein when said adjuvant binds to CD40 of a B-lymphocyte cell said adjuvant helps in activating said B-lymphocyte cell;

wherein the vaccine promotes Ig secretion and isotype switching; and

wherein the vaccine does not comprise an exogenous cytokine.

26. The vaccine of Claim 25 wherein said adjuvant and said antigen are joined together.

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27. The vaccine of Claim 24 wherein said adjuvant and said antigen are joined together.